



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,828	03/30/2004	Theoharis C. Theoharides	51275/149	3053
28538	7590	08/28/2006	EXAMINER	
DR. MELVIN BLECHER 4329 VAN NESS ST., NW WASHINGTON, DC 20016			LEITH, PATRICIA A	
			ART UNIT	PAPER NUMBER

1655

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/811,828		THEOHARIDES, THEOHARIS C.	
	Examiner		Art Unit	
	Patricia Leith		1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 40-45 are pending in the application.

Election/Restrictions

Applicant's election with traverse of the species of quercetin and chondroitin sulfate in the reply filed on 6/21/06 is acknowledged. The traversal is on the ground(s) that 1) quercetin, myrcetin and genestein all share a common core structure. However, it is noted that claims 40, 41 and 44 are directed toward any flavonoid which do not all share the same core structure as quercetin. This argument is further not found persuasive because applicant has not specifically stated on the record that each of quercetin, myrcetin and Einstein would be obvious variants of each other. Accordingly, Applicant's arguments with regard to proteoglycans was also not found persuasive because all proteoglycans do not share the same core structure as chondroitin sulfate, and again, Applicant has not specifically stated that all proteoglycans would be obvious variants.

The requirement is still deemed proper and is therefore made FINAL.

Claims 40-45 were examined on their merits.

Amendments

It is noted that Applicant is not following correct amendment format upon submission of claims. Correct amendment format includes the listing of all claim numbers, whether cancelled, withdrawn or amended, along with the correct status identifiers of the claims; e.g.:

Claims 1-39 (cancelled)

Claim 40 (original) and so forth.

It is noted that text of cancelled claims should not be recited, however, text of withdrawn claims should be recited.

Detailed instructions on how to prepare an amendment can be found at <http://ptoweb.uspto.gov/ptointranet/index.htm>.

Applicant is asked to correct the format of the claims upon response to this Office Action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40-43 and 45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. US 6,645, 482 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of '482 recites a composition comprising chondroitin sulfate, olive kernel extract, quercetin and bitter willow bark extract. Although claim 1 of '482 does not specifically recite the amounts of constituents in claim 43 of the Instant claims, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

Claims 40-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-40 of copending Application No. 10/439,301. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the claims of '301 specifically describe a composition comprising bitter willow extract, olive kernel extract, chondroitin sulfate and quercetin for treating superficial vasodilator (flush) syndrome (see specifically claim 9 of '301 for example). Although the claims of '301 do not specifically recite the amounts of constituents in claim 43 of the Instant claims, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 40-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/610,909. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1-39 of '909 specifically teach a composition comprising bitter willow extract, olive kernel extract, chondroitin sulfate and quercetin for treating superficial vasodilator (flush) syndrome (see

specifically claim 9 of '301 for example). Although the claims of '909 do not specifically recite the amounts of constituents in claim 43 of the Instant claims, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 40-43 and 45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 40 of copending Application No. 10/652,312. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 40 of '312 specifically recites a composition comprising bitter willow extract, olive kernel extract, chondroitin sulfate and quercetin for treating superficial vasodilator (flush) syndrome (see specifically claim 9 of '301 for example). Although the claim 40 of '312 does not specifically recite the amounts of constituents in claim 43 of the Instant claims, it has been held that where

the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 40-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/811,838. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1-39 of '838 specifically teach a composition comprising bitter willow extract, olive kernel extract, chondroitin sulfate and quercetin for treating superficial vasodilator (flush) syndrome (see specifically claim 9 of '838 for example). Although the claims of '838 do not specifically recite the amounts of constituents in claim 43 of the Instant claims, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d

454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 40-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/811,859. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1-39 of '859 specifically teach a composition comprising bitter willow extract, olive kernel extract, chondroitin sulfate and quercetin for treating superficial vasodilator (flush) syndrome (see specifically claim 9 of '859 for example). Although the claims of '859 do not specifically recite the amounts of constituents in claim 43 of the Instant claims, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because

concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 40-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/811,825. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-39 of '825 specifically teach a composition comprising bitter willow extract, olive kernel extract, chondroitin sulfate and quercetin for treating superficial vasodilator (flush) syndrome (see specifically claim 9 of '825 for example). Although the claims of '825 do not specifically recite the amounts of constituents in claim 43 of the Instant claims, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 40-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/811,826. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-39 of '826 specifically teach a composition comprising bitter willow extract, olive kernel extract, chondroitin sulfate and quercetin for treating superficial vasodilator (flush) syndrome (see specifically claim 9 of '826 for example). Although the claims of '826 do not specifically recite the amounts of constituents in claim 43 of the Instant claims, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 40-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of copending Application No. 10/811,839. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-39 of '839 specifically teach a composition comprising bitter willow extract, olive kernel extract, chondroitin sulfate and quercetin for treating superficial vasodilator (flush) syndrome (see specifically claim 9 of '839 for example). Although the claims of '839 do not specifically recite the amounts of constituents in claim 43 of the Instant claims, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Priority

Applicant, in the most recent amendment has stated that this application claims benefit of priority to several other applications. However, at this time, Applicant does not have benefit of priority to any other applications because applicant has not satisfied the requirements of 37 CFR 1.78 for the following reasons: A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e),

120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Therefore, for purposes of applying prior art, the actual filing date of 3/30/04 was used.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition and method for treating inflammation, does not reasonably provide enablement for treating 'flush syndrome'. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because effective treatments for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds

to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments.

In the Instant case, Applicant is claiming a composition and method for treating flush syndrome. It appears, from the prior art, that Flush syndrome is associated with vasodilatation. It is noted that there are no working examples present in the Instant disclosure, nor is there any explanation why the composition of the claims would provide for any relief from flush. The state of the art, again, reflects that 'flush' is associated with vasodilatation (widening of blood vessels) which leads to a greater flow in blood to the extremities such as the hands and face for example, which results in a 'blushing' or redness of the skin. Each compound required for the claims is a known anti-inflammatory agent. Anti-inflammatory agents are known to have vasodilating properties. Thus, it is not understood how agents which have vasodilating properties would have any effect on flush due to vasodilatation.

Due to this scientific discrepancy, as well as the lack of teachings in the Specification with regard to how to use the composition of the claims in treating flush, the skilled artisan would have to perform undue experimentation, involving rigorous trial and error protocols in order to practice the claimed invention with regard to their intended scope.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 40-43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ronca et al. (1998) in view of Gelber et al. (US 6, 576, 267 B2) in view of Noblie et al. (US 4, 265, 823) (in light of Dr. Duke's Phytochemical and Ethnobotanical Database*) in view of Sang (US 6,331,305).

Ronca et al. (1998) studied some biochemical mechanisms of the well-known anti-inflammatory activity of chondroitin sulfate (see Abstract, Intro, Table 1, Table III and Table IV for example).

Ronca et al. did not propose a composition comprising chondroitin sulfate along with quercetin, an olive kernel extract, or bitter willow bark extract.

Gelber et al. (US 6,576,267 B2) disclosed that quercetin was an effective anti-inflammatory agent (see col. 5, lines 64-66).

Noblie et al. (US 4, 265, 823) disclosed that estrole is a steroid which displayed anti-inflammatory properties (col. 10, lines 20-37). The claims state 'olive kernel extract'. Giving the phrase its broadest interpretation within reason, lacking any specific definition in the Instant specification, it is deemed that an 'olive kernel extract' may be a crude extract, or an isolated phytochemical from the olive kernel (seed). Estrole is a compound endogenous to olive kernel (see for example, Dr. Duke's Phytochemical and Ethnobotanical Database*, page 2 of internet print-out). It is noted that the claims state that the composition *optionally* includes an olive kernel extract. Thus, this rejection could have been formulated without this reference.

Sang (US 6,331,305) specifically teaches that bitter willow bark extract was known in the art for possessing anti-inflammatory properties (see col. 1, line 66- col.21, line 3).

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

In the Instant case, all of the above-listed ingredients were known anti-inflammatory agents. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial in treating any inflammatory condition including brain inflammation in multiple sclerosis patients.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating inflammation. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent as in claim 42, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

*This reference is cited merely to relay an endogenous property of olive kernel and is not used as a basis for rejection *per se*.

No Claims are allowed.

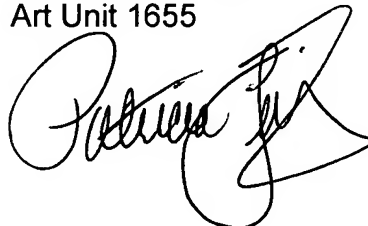
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

August 18, 2006

Patricia Leith
Primary Examiner
Art Unit 1655

A handwritten signature in black ink, appearing to read 'Patricia Leith', with a large, stylized flourish at the end.